

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PHARMASTEM THERAPEUTICS, INC.,

Plaintiff,

v.

VIACELL, INC., OBSTETRICAL AND
GYNECOLOGICAL ASSOCIATES, P.A.,
FEMPARTNERS, INC., and CARITAS ST.
ELIZABETH'S MEDICAL CENTER OF
BOSTON, INC.,

Defendants.

CIVIL ACTION NO. 04-11673 (RWZ)

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO STAY PROCEEDINGS**

Defendants ViaCell, Inc. ("ViaCell"), Obstetrical Gynecological Associates, P.A. ("OGA"), FemPartners, Inc. ("FemPartners"), and Caritas St. Elizabeth's Medical Center of Boston, Inc. ("St. Elizabeth's") submit this memorandum of law in support of their Motion to Stay Proceedings.

INTRODUCTION

In this one of several lawsuits initiated by the plaintiff, PharmaStem Therapeutics, Inc. ("PharmaStem"), the amended complaint alleges infringement of two of a series of patents held by PharmaStem, U.S. Patent No. 6,461,645 B1 ("the '645 Patent") and U.S. Patent No. 6,569,427 ("the '427 Patent"). These patents generally relate to compositions and methods involving the preservation of stem cells derived from human umbilical cord blood and therapeutic uses of such cells. As other similar proceedings relating to the same or related

patents are currently ongoing in other district courts, the defendants involved in those actions have jointly filed a motion with the Judicial Panel on Multidistrict Litigation (the “Judicial Panel”) to coordinate all of the actions, as well as an additional action regarding PharmaStem’s conduct in making baseless threats of patent infringement, to be consolidated in the District of Delaware for coordinated pretrial proceedings. *In re PharmaStem Therapeutics Patent Litigation*, MDL No. 1660.

Each one of the actions relates to at least two of PharmaStem’s patents, all of which are derived from a single parent application, serial no. 07/119,746, filed November 12, 1987. The specifications of each patent are substantially identical, there is great similarity among the claims¹, and the relevant prior art as to each patent is identical. Thus, the defendants have sought to consolidate these numerous cases in order to avoid inconsistent rulings and to promote judicial efficiency.

¹ Exemplary claims in the PharmaStem patents include:

<p>‘681 Patent – Claim 1 reads: “[a] cryopreserved therapeutic composition comprising: viable human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a single human collected at the birth of said human, in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult; and an amount of cryopreservative sufficient for cryopreservation of said cells.”</p>	<p>‘645 Patent – Claim 1 reads: “A cryopreserved pharmaceutical composition comprising (a) viable human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or the placental blood of a single human collected at the birth of said human, in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult; (b) an amount of cryopreservative of said cells; and (c) a pharmaceutically acceptable carrier.”</p>
<p>‘533 Patent – Claim 13 reads: “A method for hematopoietic or immune reconstitution of a human comprising: (1) isolating human neonatal or fetal blood components containing hematopoietic stem cells; (b) cryopreserving the blood components; (c) thawing the blood components; and (d) introducing the blood components into a suitable human host, such that the hematopoietic stem cells are viable and can proliferate within the host.</p>	<p>‘427 Patent – Claim 1 reads: “A method for treating a human patient in need of hematopoietic reconstitution comprising introducing into the human patient a composition comprising a cryoprotective agent and human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a human collected at birth of said human so as to provide hematopoietic reconstitution.”</p>

The defendants in the other related actions have also sought a stay of proceedings pending the decision of the Judicial Panel. In fact, PharmaStem's Florida Action was stayed *sua sponte* for 120 days to permit the Judicial Panel to consider the pending motion and to allow "one court [to] construe the patents [and] to maintain judicial economy." See Exhibit A at 19:17-23 attached hereto to the Declaration of Terese Dillingham. Likewise, a stay of this action is appropriate pending the ruling of the Judicial Panel. Accordingly, and for the reasons set forth in this Memorandum, defendants' motion should be granted.

FACTUAL BACKGROUND

In February 2002, PharmaStem filed suit in the District of Delaware against ViaCell, a private umbilical cord blood bank, and other cord blood banks (the "Delaware Action"), alleging the infringement of U.S. Patents Nos. 5,004,681 ("the '681 Patent") and 5,192,553 ("the '553 Patent"). *PharmaStem Therapeutics, Inc. v. ViaCell, Inc., et al*, C.A. No. 02-148-GMS. The case went to trial before the Honorable Gregory M. Sleet, United States District Judge for the District of Delaware in October 2003. The jury returned its verdict in favor of PharmaStem, finding that the '681 Patent and the '553 Patent were valid and that the defendants had infringed the patents. On September 15, 2004, Judge Sleet ruled on the parties' post-trial motions finding, *inter alia*, that the defendants were entitled to judgment as a matter of law regarding the alleged infringement of the '553 Patent and that defendants were entitled to a new trial regarding the alleged infringement of the '681 Patent. Defendants filed a motion for partial reconsideration of the Court's post-trial rulings requesting that the Court enter judgment as a matter of law in favor of defendants regarding the alleged infringement of the '681 Patent. On December 7, 2004,

during a telephone conference with the parties and on the case docket, Judge Sleet indicated that the relief requested by defendants in their partial motion for reconsideration would be granted. An opinion granting defendants judgment as a matter of law regarding the alleged infringement of the '681 Patent is expected any day.²

Furthermore, while the post-trial motions in the Delaware Action were pending, on July 2, 2004, Judge Sleet issued a preliminary injunction order against PharmaStem. Judge Sleet found that certain statements made by PharmaStem, in an effort to dissuade obstetricians from collecting umbilical cord blood for their patients who were customers of the defendants, were false and misleading, and PharmaStem was enjoined from making further false and misleading statements directed to obstetricians.³

In response to Judge Sleet's July 2 Order, PharmaStem filed five new actions in July and August 2004 in separate district courts for infringement of the '681 Patent, and/or the '427 Patent and the '645 Patent. *See PharmaStem Therapeutics, Inc. v. Cord Blood Registry, Inc., et al.*, C.A. No. C-04-3072-JSW (N.D. Cal.) (the "Northern California Action") (asserting infringement of the '427 Patent and the '645 Patent); *PharmaStem Therapeutics, Inc. v. CureSource, Inc., et al.*, C.A. No. SA-CV-04-921-GLT (C.C. Cal.) (the "Central California Action") (asserting infringement of the '681 Patent, the '427 Patent, and the '645 Patent); *PharmaStem Therapeutics, Inc. v. Corcell, Inc., et al.*, C.A. No. 2:04-CV-03561-RK (the "Pennsylvania Action") (asserting infringement of the '427 Patent and the '645 Patent);

² The issues that were dispositive on these points are directly relevant to issues of infringement of the '427 and the '645 Patents, which are the subject of this action.

³ Subsequent motions raising issues of contempt of the July 2 Order have been briefed and argued and are pending before Judge Sleet.

PharmaStem Therapeutics, Inc. v. CryoCell International, Inc., et al., C.A. No. 8:04-CV-1740-T-30TGO (M.D. Fla.)(the “Florida Action”) (asserting infringement of the ‘427 Patent and the ‘645 Patent); and the instant action in this Court (asserting infringement of the ‘427 Patent and the ‘645 Patent). All of these actions targeted physicians, medical groups, and/or health care facilities in addition to the private umbilical cord banks that had not agreed to license PharmaStem’s patents. On October 5, 2004, ViaCell filed a separate action in the District of Delaware against PharmaStem, asserting claims of antitrust and Lanham Act violations as well as claims for tortious interference and for unfair and deceptive trade practices arising from PharmaStem’s efforts to require obstetricians to agree to refrain from conduct that is beyond the scope of PharmaStem’s patents as a condition of avoiding suit for infringement. *ViaCell, Inc. v. PharmaStem Therapeutics, Inc.*, C.A. 04-1335-GMS (D. Del.). CorCell and Cryo-Cell International, Inc. were added to that case as plaintiffs by an amended complaint.

In response to PharmaStem’s numerous lawsuits, ViaCell and the other defendants in PharmaStem’s infringement cases jointly filed a motion for consolidation and coordination of all of these cases for pretrial proceedings before Judge Sleet in Delaware. The Judicial Panel deemed the motion to consolidate filed on November 2, 2004, the motion has been fully briefed, and the parties are awaiting the Judicial Panel’s decision.

Defendants in the Northern California action as well as the Pennsylvania action have likewise filed motions to stay the proceedings pending the decision by the Judicial Panel and those motions are currently pending in those courts. Further, on November 9, 2004, Hon. James Moody of the Middle District of Florida *sua sponte* entered an order staying proceedings in PharmaStem’s Florida Action for 120 days to permit the Judicial Panel to consider the pending

motion and to avoid a waste of resources of the court and parties in the interim. Judge Moody expressed his view that “one court should construe the patents to maintain judicial economy.” See Exhibits A and B attached hereto to the Declaration of Terese Dillingham.

ANALYSIS

In determining whether to stay a pending proceeding, the Court must “weigh competing interests and maintain an even balance.” *Landis v. North American Co.*, 299 U.S. 248, 254-55 (1936). Among those competing interests are the economy of time and effort for the Court, counsel and the litigants as well as the hardship or inequity which a party may suffer in being required to go forward. *Id.* The Court has broad discretion in determining whether to stay litigation in order to conserve judicial resources and promote the efficient and comprehensive disposition of cases. *I.A. Durbin, Inc. v. Jefferson Nat. Bank*, 793 F.2d 1541, 1551-52 (11th Cir. 1986); *Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183 (1952); *id.* And specifically, the Court has the authority to stay all proceedings pending the decision by the Judicial Panel on Multidistrict Litigation. See *Hertz Corp. v. The Gator Corp.*, 250 F.Supp.2d 421, 426 (D.N.J. 2003); see also, *Moore v. Wyeth-Ayerst Labs.*, 236 F.Supp.2d 509, 511 (D. Md. 2002).

The general rule is to avoid duplicative litigation between federal district courts in order “to avoid the waste of duplication, to avoid rulings which may trench upon the authority of sister courts, and to avoid piecemeal resolution of issues that call for a uniform result.” *Boston and Maine Corp. v. United Transp. Union*, 110 F.R.D. 322, 328 (D.Mass. 1986); see also, *Colorado River Water Conservation District v. United States*, 424 U.S. 800, 817 (1976); 5C Fed. Prac. & Proc. Civ. 3d § 1360 (2004). Courts have agreed that “duplicative” does not mean “identical.”

I.A. Durbin, 793 F.2d at 1551; *Landis*, 299 U.S. at 254. Rather suits are considered duplicative if the parties, issues, or relief requested do not differ significantly. *I.A. Durbin*, 793 F.2d at 1551; *Ridge Gold Standard Liquors v. Seagram*, 572 F.Supp. 1210, 1213 (N.D. Ill. 1983); *Boston and Maine Corp. v. United Transp. Union*, 110 F.R.D. 322, 329-30 (D.Mass. 1986) (“substantial overlap between suits”).

Here, all of the factors weigh in favor of granting a stay of the proceedings. A stay in this action would permit the Judicial Panel to determine whether these numerous cases can be consolidated in a more efficient manner to provide more consistent rulings. Thus, a stay in this case would clearly promote judicial efficiency, lessen the burden on the parties as well as the courts imposed by proceeding in the several jurisdictions, and no prejudice to PharmaStem would be caused by the stay. In addition, the stay sought here is a limited one, until the decision of the Judicial Panel on the pending motion to consolidate for coordinated pretrial proceedings.

Absent a stay in this action, there is a significant concern for inconsistent rulings regarding issues raised by the several lawsuits filed by PharmaStem. Specifically, one major concern arising from simultaneous proceedings in different district courts in cases involving the same patents is that PharmaStem would be able to conduct parallel claim construction hearings and thus create the risk of inconsistent claim constructions rulings among the courts. In addition, given the overlap of factual questions and the similarity of the claims and defenses, discovery in these lawsuits will cover a substantial number of common issues. Thus, discovery – and resulting motion practice – could significantly duplicate itself. Such repetitive discovery could also impose substantial burdens on witnesses, many of whom would be subject to multiple depositions regarding the same issues in different fora. Such inconsistency and duplication

would unduly burden the parties and needlessly waste judicial resources.

Furthermore, PharmaStem would not suffer any prejudice or injury as a result of the stay. Defendants have not yet filed a response to PharmaStem's amended complaint and no discovery has taken place in this action. The only activity that has occurred in this case are PharmaStem's Motions for a Temporary Restraining Order and a Permanent Injunction enjoining ViaCell from taking further action in the more recent Delaware action, Civ. Action No. 04-1334-GMS. Thus, these two motions do not seek to impact the course of this action but instead seek to impact the action pending in Delaware. In addition, these motions are now fully briefed, argument has been heard, and the Court has taken these motions under advisement. Furthermore, PharmaStem's claims will be adequately addressed after the stay is lifted, whether in this Court or the transferee court. *See Hertz*, 250 F.Supp.2d at 426 (granting motion to stay pending motion before the Judicial Panel because the party opposing the stay could secure effective relief once the stay was terminated). As a result, PharmaStem will not be prejudiced should the Court grant defendants' motion for a stay.

Indeed, as noted above, one of the actions filed by PharmaStem, the Florida Action, has already been stayed pending the ruling of the Judicial Panel. *See Exhibit A*. Likewise, a stay of this case is appropriate to permit the Judicial Panel to determine whether these numerous actions can be consolidated to provide greater efficiency and consistency. Thus, the practical effect of a stay in this action would serve to promote judicial efficiency, lessen the burden on all parties, and would not cause any prejudice to PharmaStem. Therefore defendants' motion for a stay should be granted.

CONCLUSION

For all of the foregoing reasons, defendants respectfully request that this Court grant a stay of all proceedings pending the ruling of the Judicial Panel on Multidistrict Litigation.

Respectfully submitted,

VIACELL, INC., OBSTETRICAL AND
GYNECOLOGICAL ASSOCIATES, P.A.,
FEMPARTNERS, INC., and CARITAS ST.
ELIZABETH'S MEDICAL CENTER OF
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